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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,758	12/21/2001	James A. Brady	9386.17711-E	4470

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,758	BRADY ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *numerous*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 29-32 in the reply filed on January 18, 2005 is acknowledged.

Claims 1-28 have been cancelled, accordingly, claims 29-32 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. Claims 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 29-32 recite a method for treating an individual experiencing a condition on a continuum from early sepsis to septic shock comprising the steps of drawing the blood from the circulatory system of the individual for return to the circulatory system, and removing ***cytokines or other species of pro-inflammatory or anti-inflammatory stimulators or mediators*** from the blood by brining the blood into contact with an ***adsorption medium sized to selectively adsorb cytokines or other species of pro-inflammatory or anti-inflammatory stimulators or mediators from the blood***, the adsorption medium being characterized by a Biocompatibility Index of not greater than 14. (Emphasis added).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants,

and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "cytokines or other species of pro-inflammatory stimulators or mediators" and "adsorption medium sized to selectively adsorb..." alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Furthermore, given that the structural identity of "other species of pro-inflammatory stimulators or mediators" is not set forth, one of skill in the art would have difficulty selecting an adsorption medium "sized to selectively adsorb" these molecules without some guidance as to the structure or size or properties of these molecules in order to "selectively adsorb them."

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

2. Claim 29 recites the limitation "the blood" in line 3. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

3. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of an improper Markush claim. The claims lists two members and ends with the punctuation mark of a comma. Are other members intended to be recited or should the claim end with an "and N-vinylpyrrolidine." Clarification is requested.

3. Claims 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of a "Biocompatibility Index of not greater than 14 or 7."

Applicants specification sets forth of methods for determining the Biocompatibility Index, however these are merely examples of ways that the index may be calculated. Any number of methods or parameters may be used to calculate arbitrary numbers. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, without a specific definition of the term "biocompatibility index" one of skill in the art would be unable to determine the metes and bounds of the term "biocompatibility index of not greater than 14 or 7."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Matson et al.

The claims are directed to a method for treating an individual experiencing a condition on a continuum from early sepsis to septic shock comprising the steps of drawing the blood from the circulatory system of the individual for return to the circulatory system, and removing cytokines or other species of pro-inflammatory or anti-inflammatory stimulators or mediators from the blood by brining the blood into contact with an adsorption medium sized to selectively adsorb cytokines or other species of pro-inflammatory or anti-inflammatory stimulators or mediators from the blood, the adsorption medium being characterized by a Biocompatibility Index of not greater than 14.

Matson et al (US Patent Number 6,287,516) disclose of a hemofiltration system used to treat an inflammatory mediator related disease such as sepsis and septic shock. (See claims). Matson et al disclose adsorption of the inflammatory mediators from an ultrafiltrate stream that cause inflammatory mediator related diseases to create a post adsorption ultrafiltrate system and combining the ultrafiltrate stream with a filtered

blood stream and returning the filtered blood/ultrafiltrate to the blood stream mammal. (See abstract). The inflammatory mediators of Matson et al include cytokines and endotoxins. (See column 2, lines 36-65). Matson et al further disclose that the adsorbent material may be comprised of a host of materials including but not limited to uncharged resins, charged resins, immobilized polymyxin B, anion exchange resin, cation exchange resin, neutral exchange resin, polysuflone, polyacrylonitirile, polymethylmethacrylate, polyvinyl-alcohol, polyamide, polycarbonate, cellulose derivatives, etc. (See column 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al in view of Davankov et al.

The claims are directed to a method for treating an individual experiencing a condition on a continuum from early sepsis to septic shock comprising the steps of drawing the blood from the circulatory system of the individual for return to the circulatory system, and removing cytokines or other species of pro-inflammatory or anti-inflammatory stimulators or mediators from the blood by brining the blood into contact with an adsorption medium sized to selectively adsorb cytokines or other species of pro-inflammatory or anti-inflammatory stimulators or mediators from the blood, the adsorption medium being characterized by a Biocompatibility Index of not greater than 14, and wherein the adsorption medium comprises a polymeric material formed from a porous hydrophobic divinylbenzene copolymer.

The teachings of Matson et al are set forth above.

Matson et al do not teach of an adsorption medium compriseing a polymeric material formed from a porous hydrophobic divinylbenzene copolymer.

Davankov et al (US Patent Number 5,773,384) teach of a novel resin for removing blood toxicants comprising a hypercrosslinked styrene resin having a surface modified and heparin electrostatically bound to form an aqueous solution onto the beads with chrlormethyl groups substituted by amino functions through reaction with amines and 2-ethanolamine in particular. Davankov et al also teach a variety of shell structures that provide for chemical modification of the polystyrene resins to enhance hemocompatibility of the material and include copolymers comprising methylacrylate

(see columns 8-9) and polymerization of various hydrophilic monomers, such as hydroxyethylmethacrylate (See column 6) to provide for enhanced biocompatibility. Davankov et al specifically teach sorbents that are styrene-divinylbenzene copolymers. (See claims).

It would have been prima facie obvious to one having ordinary skill in the art to use the sorbents of Davankov et al in addition to the sorbents described by Matson et al in the adsorbent cartridge of Matson et al because Davankov et al teach that the sorbents are useful for removing blood toxicants. It would have been further prima facie obvious to coat any of the adsorbents with a semipermeable polymeric coating such as hydroxyethylmethacrylate to provide for enhanced biocompatibility of the sorbents. One would have been motivated to incorporate such a sorbent based upon the teachings of Davankov et al that such mediums provided enhanced biocompatibility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
April 11, 2005